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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,454	03/05/2002	Gregory M. Podsakoff	0800-0009.08	9403

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 01/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/092,454

Applicant(s)

PODSAKOFF ET AL.

Examiner

Anne Marie S. Wehbe

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,7-12 and 16-20 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3,4,7-12,16,18 and 20 is/are allowed.
- 6) ☒ Claim(s) 17 and 19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

As noted in the communication mailed 7/6/04, the applicant is advised that the Notice of Allowance mailed on 2/23/04 has been **vacated**. If the issue fee has already been paid, applicant may request a refund or request that the fee be credited to a deposit account. However, applicant may wait until the application is either found allowable or held abandoned. If allowed, upon receipt of a new Notice of Allowance, applicant may request that the previously submitted issue fee be applied. If abandoned, applicant may request refund or credit to a specified Deposit Account.

Claims 1, 3-4, 7-12, and 16-20 are pending in the instant application. Prosecution on the merits of this application is **reopened on claims 17 and 19**, considered unpatentable for the reasons indicated below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17 and 19 are rejected under 35 U.S.C. 102(e) as being US Patent Application Publication 2002/0192189 A1 (Dec. 19, 2002), hereafter referred to as Xiao et al. Xiao et al. has an effective filing date of June 7, 1995. The instant application has an effective filing date of 1/18/96. While the applicant has submitted a declaration under 37 CFR 1.131 which establishes that the applicant was in possession of the invention "prior to" September 27, 1995, the Xiao et al. publication's effective filing date of June 7, 1995, precedes the established date of possession by the applicants. As such, Xiao et al. qualifies as 102(e) art over claims 17 and 19.

The applicant claims a method of treating an acquired or inherited disease in a mammal by introducing into an *in vivo* muscle cell or tissue of the mammal a therapeutically effective amount of recombinant AAV virions comprising an AAV vector comprising a selected gene operably linked to control elements capable of directing the transcription and translation of the gene in the mammal, and a method for delivering a therapeutically effective amount of a protein systemically to a mammal by introducing into an *in vivo* muscle cell or tissue of the mammal a therapeutically effective amount of recombinant AAV virions comprising an AAV vector comprising a selected gene operably linked to control elements capable of directing the transcription and translation of the gene in the mammal.

Xiao et al. teaches methods of expressing gene products in muscle tissue of an animal comprising administering a recombinant AAV vector which comprises a non-AAV gene encoding a protein operably linked to a promoter operable in muscle tissue by intramuscular injection (Xiao et al., column 6, claims 1-11). Xiao et al. further teaches an AAV "vector" means a vector DNA packaged into viral coat proteins, e.g. a virion (Xiao et al., page 3, paragraph 0136). In addition, Xiao et al. teaches that the gene to be expressed by the recombinant AAV

includes genes associated with disease, such that the delivery and expression of the gene by the recombinant AAV results in gene therapy of the disease (Xiao et al., page 4, paragraph 0145). Specifically, Xiao et al. teaches diseases such as hemophilia, diabetes, and Gaucher's disease (Xiao et al., page 4, paragraph 0145). Xiao et al. also teaches that the gene product can be secreted and that the vascular system of the host can deliver the gene product to other parts of the body, i.e. systemically (Xiao et al., page 4, paragraph 0144-0145). Thus, by teaching all the limitations of the claims as written, Xiao et al. anticipates the instant invention as claimed.

Claims 1, 3-4, 7-12, 16, 18, and 20 remain allowable over the prior art of record at this time. Please note that Xiao et al. has not been applied to claims 1, 3-4, 7-12, 16, 18, or 20 because Xiao et al. does not teach or suggest introducing recombinant AAV into cardiac tissue or smooth muscle tissue, and further does not suggest introducing recombinant AAV into muscle cells *in vitro* following by the transplantation of the cells into a mammal for therapy of disease.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 9:30-6:00 EST. If the examiner is not available, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. For all official communications, **the new technology center fax number is (571) 273-8300**. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

